



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2001-D-0067 (formerly Docket No. 2001D-0185)]

Draft Guidance for Industry on Providing Submissions in Electronic Format--Postmarketing Safety Reports; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Providing Submissions in Electronic Format--Postmarketing Safety Reports." This draft guidance provides general information pertaining to electronic submission of postmarketing safety reports (individual case safety reports (ICSRs), attachments to ICSR (ICSR attachments), and other postmarketing safety reports) for certain human drug and biological products. We are issuing the draft guidance to help persons required to submit postmarketing safety reports comply with the final rule.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002, or to the

Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-7800. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For information concerning human drug products: Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4466, Silver Spring, MD, 20993-0002, 301-796-1874.

For information concerning human biological products: Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 7268, Silver Spring, MD, 20993-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Providing Submissions in Electronic Format--Postmarketing Safety Reports." This draft guidance provides general information pertaining to electronic submission of postmarketing safety reports (ICSRs, ICSR attachments, and other postmarketing safety reports) for the following products:

- Drug products marketed for human use with approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs);
- Prescription drug products marketed for human use without an approved NDA or ANDA;
- Biological products, other than vaccines, marketed for human use with approved biologic license applications (or BLAs);
- Nonprescription (over-the-counter or OTC) human drug products marketed without an approved application.

This draft guidance does not apply to vaccines, human cells, tissues, and cellular and tissue-based products regulated under section 361 of the Public Health Service Act, whole blood, components of whole blood, or lot distribution reports.

This draft guidance revises and replaces the draft guidance for industry entitled "Providing Regulatory Submissions in Electronic Format--Postmarketing Individual Case Safety Reports," issued on June 12, 2008 (73 FR 33436). Elsewhere in this issue of the Federal Register, we are publishing a final rule to require that mandatory postmarketing safety reports for human drug and biological products be submitted to FDA in an electronic format that the Agency can process, review, and archive. The revised draft guidance is intended to help persons subject to mandatory postmarketing safety reporting requirements comply with the final rule. Along with other information, the revised draft guidance provides updated information about the following: (1) Options for submitting postmarketing safety reports to FDA in electronic format, (2) the notification that submitters will receive when FDA has received the electronic postmarketing safety report, and (3) procedures for requesting temporary waivers from the electronic submission requirement.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on submission of postmarketing safety reports in electronic format. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

The information collection resulting from this draft guidance is covered by the information collection provisions of the final rule entitled "Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements," which is published elsewhere in this issue of the Federal Register. The information collection provisions of the final rule have been submitted to the Office of Management and Budget (OMB) for review, as required under section 3507(d) of the Paperwork Reduction Act. Prior to the effective date of the final rule, FDA will publish a notice in the Federal Register announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IV. Electronic Access

Persons with access to the Internet may obtain the document at

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>,
[http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/
default.htm](http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm), or <http://www.regulations.gov>.

Dated: June 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014-13479 Filed 06/09/2014 at 8:45 am; Publication Date: 06/10/2014]